

Message Text

UNCLASSIFIED

PAGE 01 STATE 215785
ORIGIN HEW-06

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FM SECSTATE WASHDC
TO AMEMBASSY MANILA PRIORITY

UNCLAS STATE 215785

E.O. 11652: N/A

TAGS: ETRD, SWEL, TBIO RP

SUBJECT: STATUS OF DIAL SOAP IN THE UNITED STATES
REFERENCE: MANILA 13779

1. "DIAL" SOAP IS MARKETING IN LIQUID FORM AND IN BAR FORM UNDER DIFFERENT FORMULATIONS AND WITH DIFFERENT ACTIVE INGREDIENTS. FDA RESTRICTIONS ARE BASED ON THE ACTIVE INGREDIENT.
 2. HEXACHLOROPHENE IS THE ACTIVE INGREDIENT IN DIAL CONCENTRATE LIQUID SOAP (0.75 PERCENT HEXACHLOROPHENE) AND DIAL READY-TO-USE LIQUID HEXACHLOROPHENE SOAP (0.25 PERCENT HEXACHLOROPHENE). THE DIAL LIQUID SOAP PRODUCTS ARE BACTERIOSTATIC INTENDED FOR HANDWASHING AT THE DIRECTION OF A PHYSICIAN. THEY ARE PRESCRIPTION DRUGS.
 3. A FINAL RULE PUBLISHED IN THE FEDERAL REGISTER OF DECEMBER 20, 1977 (42FR63771) PROHIBITED MARKETING OF UNCLASSIFIED
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- HEXACHLOROPHENE CONTAINING NEW DRUGS NOT APPROVED BY JANUARY 31, 1978. THIS WOULD INCLUDE PRODUCTS SUCH AS DIAL LIQUID WITH CONCENTRATIONS OF HEXACHLOROPHENE GREATER THAN 0.1 PERCENT FOR USE AS A SURGICAL SCRUB AND FOR TOPICAL APPLICATION.
4. DIAL CONCENTRATE LIQUID SOAP (U.75 PERCENT HEXA-

CHLOROPHENE) "IS NOT" REPEAT "IS NOT" SUBJECT OF AN APPROVED NEW DRUG APPLICATION AND AN ADMINISTRATIVE STAY OF THE FINAL RULE EXPIRED AUGUST 1, 1978 AND WILL NOT BE RENEWED.

5. DIAL READY TO USE LIQUID HEXACHLOROPHENE SOAP (0.25 PERCENT HEXACHLOROPHENE) "IS" REPEAT "IS" THE SUBJECT OF AN APPROVED NEW DRUG APPLICATION AND CAN BE MARKETING AS A PRESCRIPTION BACTERIOSTATIC SKIN CLEANSER IN THE UNITED STATES.

6. DIAL BAR SOAP CONTAINING TRICLOCARBAN (TCC, 3,4,4-TRICHLOROCARBANILIDE) IS CURRENTLY MARKETING TO THE GENERAL PUBLIC WITHOUT RESTRICTION FOR USE AS A HEALTH CARE OR ANTIMICROBIAL SOAP. TRICLOCARBAN (TCC) IS AN INGREDIENT UNDER EVALUATION BY THE OVER-THE-COUNTER ANTIMICROBIAL I PANEL. ADEQUATE DATA ARE NOT YET AVAILABLE TO PERMIT FINAL CLASSIFICATION OF TCC FOR USE IN BAR SOAP. THE AVAILABLE EVIDENCE DOES NOT INDICATE THAT THE USE OF TCC IN BAR SOAPS PRESENTS ANY KNOWN HAZARD TO THE GENERAL PUBLIC. CHRISTOPHER

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